UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	CASE NO. 5:13CV210
	)	
	)	
PLAINTIFF,	)	JUDGE SARA LIOI
	)	
vs.	)	
	)	**MEMORANDUM OPINION**
BRIAN D. HEIM, M.D.,	)	**AND ORDER**
	)	
	)	
DEFENDANT.	)	

Before the Court is the motion for summary judgment on liability filed by plaintiff, United States of America. (Doc. No. 13.) Defendant has not filed any opposition. For the reasons set forth herein, the motion is granted.

I. PROCEDURAL BACKGROUND

On January 29, 2013, plaintiff filed this action against defendant to recover civil penalties for alleged violations of the Comprehensive Drug Abuse Prevention Control Act of 1970, 21 U.S.C. § 801, *et seq.*, and regulations thereunder. In three counts, the complaint alleges, in relevant part:

> 2. The Defendant, Brian D. Heim, M.D., is registered under 21 U.S.C. §§ 822 and 823 as a practitioner authorized to dispense Schedule II, III, IV, and V controlled substances to the extent permitted by federal law, and has been assigned Registration Number BH7542283 by the Drug Enforcement Administration ("DEA"). Defendant is licensed under the laws of Ohio to practice medicine, and his registered location is 3562 Ridge Park Drive, Suite A, Akron, Ohio 44333.
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> * * *

COUNT I: FAILURE TO MAINTAIN PURCHASE RECORDS

* * *

14. Between August 17, 2011, and June 5, 2012, Defendant refused or negligently failed to make, keep, or furnish records of the controlled substance hydrocodone as required by 21 U.S.C. § 827(a)(3) and 21 C.F.R. § 1304.22(c) and prohibited by 21 U.S.C. § 842(a)(5).

15. This constitutes at least fourteen separate violations of 21 U.S.C. § 842(a)(5) . . . .

* * *

COUNT II: FAILURE TO MAINTAIN DISPENSING RECORDS

* * *

19. On an unknown number of occasions between August 17, 2011 and July 16, 2012, Defendant refused or negligently failed to make, keep, or furnish dispensing records of at least 11,500 hydrocodone tablets as required by 21 U.S.C. § 827(a)(3) and 21 C.F.R. § 1304.22(c), and prohibited by 21 U.S.C. § 842(a)(5).

20. This constitutes an unknown number of violations of 21 U.S.C. § 842(a)(5) . . . . The precise number of violations will be determined at the time of trial.

* * *

COUNT III: FAILURE TO MAINTAIN BIENNIAL INVENTORY

* * *

23. Between January 1, 2011, and January 1, 2012, Defendant refused or negligently failed to make, keep, or furnish a biennial inventory of his stock of controlled substances on hand as required by 21 U.S.C. § 827(a)(1) and 21 C.F.R. §1304.11(c), and prohibited by 21 U.S.C. § 842(a)(5).

24. This constitutes a violation of 21 U.S.C. § 842(a)(5) . . . .

* * *

(Complaint, Doc. No. 1.)

On March 20, 2013, represented by counsel, defendant filed his answer, denying the allegations in ¶¶ 14, 15, 19, and 20 of the complaint, and admitting the allegations in ¶¶ 23 and 24. Although not entirely clear, the answer appears to deny the allegations in ¶ 2 of the complaint.[1] (Answer, Doc. No. 6.)

The Case Management Conference ("CMC") was convened by the Court on May 10, 2013. Counsel for plaintiff was in attendance, along with Drug Enforcement Administration ("DEA") Diversion Investigator, Scott Brinks. Defendant and his attorney also attended. The Court issued the Case Management Plan and Trial Order, setting case management dates.

On September 4, 2013, the Court conducted a status conference, with both attorneys and clients or client representatives in attendance. During that conference, counsel advised the Court that the parties were considering a settlement and, therefore, plaintiff agreed to wait until the deadline to file any dispositive motion.

On November 4, 2013, plaintiff timely filed the instant motion for summary judgment on the question of liability, which has gone unopposed.

II. DISCUSSION

A. Legal Standard

Under Fed. R. Civ. P. 56(a), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." "If a party . . . fails to properly address another party's assertion of fact as required in Rule 56(c), the court may: . . . (2) consider the fact undisputed for purposes of the motion; [and] (3) grant summary judgment if the motion and supporting materials—

[1] Paragraph 2 of the answer states: "Paragraph 2 [of the complaint] contains a statement identifying the Defendant in this action, to which no answer is required. To the extent an answer is required, the Defendant denies the allegations set forth in paragraph 1." The Court presumes the reference to "paragraph 1" is a typographical error.

including the facts considered undisputed—show that the movant is entitled to it[.]" Fed. R. Civ. P. 56(e).[2]

B. Undisputed Material Facts

In support of its motion for summary judgment, plaintiff has submitted evidentiary materials, including the declaration of Scott Brinks. (Doc. No. 13-2 ["Decl."].)

Brinks is "a duly appointed Diversion Investigator" of the DEA, who was "assigned to the Cleveland Resident Office for the last eleven years." (Decl. ¶ 2.) The material facts stated herein are supported by Brinks's declaration and are completely unrefuted by defendant.[3]

Defendant was registered under the Act as a medical practitioner and was authorized to handle controlled substances Schedules II, III, IV, and V. (*Id.* ¶ 4; *see* 21 U.S.C. §§ 822 and 823.) His registered location was 3562 Ridge Park Drive, Suite A, Akron, Ohio. (*Id.* ¶ 5.)

In 1998, Heim entered guilty pleas to twenty-four (24) felony counts of theft of drugs and twenty-one (21) felony counts of illegal processing of drug documents.[4] His medical

[2] Rule 56(c)(1)(A) requires a party to support assertions of fact by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials[.]" Rule 56(c)(4) specifies that affidavits or declarations used in support of facts "must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated."

[3] Plaintiff also asserts that all of these facts are not only unrefuted, but should be deemed admitted by defendant, under Fed. R. Civ. P. 36(a)(3), due to his complete failure to respond to plaintiff's discovery requests, in particular the requests for admissions. (*See* Motion at 88-89.) The Court agrees. Based upon plaintiff's representations, plaintiff served requests for admissions upon defendant on July 5, 2013, and, as of the time of the filing of the subject motion for summary judgment (on November 4, 2013), defendant failed to answer. Due to defendant's failure to answer the discovery, pursuant to Fed. R. Civ. P. 36(a)(3), the requests for admissions are hereby deemed admitted.

[4] The record is not clear as to where these pleas were entered.

license was suspended and he was given treatment in lieu of conviction. (*Id*. ¶ 6 and Att. 1 at 104.)

On June 6, 2012, Heim was arraigned in Summit County Court of Common Pleas on seven counts of aggravated trafficking in drugs and one count of tampering with evidence. (*Id*. ¶ 7 and Att. 2.) The drug charges were eventually dropped in return for defendant's guilty plea to one count of obstruction of justice. (*Id*. ¶ 8 and Att. 3.) He also agreed to surrender his medical license and his DEA registration as part of his plea. (*Id.* ¶¶ 9, 10.)[5] As a result, defendant is no longer permitted to dispense or prescribe Schedule II – V drugs.

On July 5, 2012, Brinks checked the DEA Automation of Reports and Consolidated Orders System ("A.R.C.O.S."), which is a DEA database used to capture the activity of controlled substances from the point of manufacture and/or distribution to the point of sale to the retail level registrant. (*Id*. ¶ 11.) This check of A.R.C.O.S. revealed that defendant was purchasing extraordinarily large amounts of hydrocodone/APAP tablets (hydrocodone and acetaminophen) from the pharmaceutical wholesaler Henry Schein, Inc. (*Id*. ¶ 12.)

On July 11, 2012, plaintiff obtained an administrative warrant to inspect, copy, and verify the correctness of defendant's records, reports, and other documents. This warrant was served on defendant on July 16, 2012. (*Id*. ¶ 13; *see* 21 U.S.C. §§ 878(a)(2) and 880, 21 C.F.R. § 1316.) That inspection, and subsequent investigation, revealed that, on fourteen separate dates between January 17, 2011 and January 4, 2012, defendant purchased a total of 11,500

[5] The written guilty plea does not include any mention of relinquishing his license or DEA registration (*see* Decl. Att. 3); however, Ohio's records of formal actions show that Heim's license was revoked on May 8, 2013, and his DEA registration was surrendered (*id*. Att. 1).

hydrocodone tablets from Henry Schein, Inc. (*Id*. ¶ 14.)[6] When defendant was asked during the inspection to produce copies of a biennial inventory for his controlled substances (required under 21 U.S.C. § 827(a)(1)), he admitted to not keeping such a record. (*Id*. ¶ 15.) When asked to produce copies of purchase records and dispensing records for the hydrocodone he received from Henry Schein, Inc. (required under 21 U.S.C. § 827(a)(3)), he failed to comply. (*Id*. ¶¶ 16, 17.) Defendant indicated that the records were at his home (although federal regulations require that such records be kept at the registered location). (*Id*. ¶¶ 18, 19; *see* 21 C.F.R. § 1304.11(a).) Defendant then went to his home to retrieve the records, but returned with only one invoice, dated March 27, 2012, for 500 tablets of hydrocodone 10/500 MG. He stated that he could not locate his dispensing log, and that he had no hydrocodone on hand. (*Id*. ¶¶ 20, 21.)

DEA's investigation revealed that defendant failed to keep any records for the hydrocodone he purchased from August 17, 2011 through June 5, 2012, and for the hydrocodone he dispensed from August 17, 2011 through July 16, 2012. (*Id*. ¶ 22.) As a result of defendant's failure to keep records, there is no record of what actually happened to the 11,500 tablets of hydrocodone from Henry Schein, Inc. (*Id*. ¶ 23.)

By letter dated September 24, 2012, DEA received a copy of what defendant claimed was his purchase log (styled "Meds In") and dispensing log (styled "Meds Out"). (*Id*. ¶ 24; Motion, Ex. C.[7]) Upon receiving these logs, Brinks interviewed six of the twelve patients listed on the "Meds Out" log, and discovered that most, if not all, of the hydrocodone dispensings never occurred. (Decl. ¶ 25.) Brinks further discovered that defendant had personally

[6] On July 11, 2012, Henry Schein, Inc. provided a summary of defendant's purchases of controlled substances between January 1, 2011 and July 11, 2012. (Motion at 86-87 and Ex. B.) This listing shows fourteen (14) purchases of hydrocodone/APAP tablets.

[7] Ex. C has been redacted to protect patient surnames. (Motion, at 87 n.3.) These same logs were provided by defendant in his initial disclosures under Fed. R. Civ. P. 26(a)(1). (Motion, Ex. D.) DEA has determined that both logs were fabricated. (Brinks Decl., ¶ 27.)

contacted at least five of his patients and requested that they tell DEA he had dispensed tablets to them in the past, even if they did not remember receiving the tablets. (*Id*. ¶ 26.)

C. Analysis

Registrants under the Comprehensive Drug Abuse Prevention Control Act of 1970,[8] 21 U.S.C. § 801, *et seq*. ("the Act"), are required to maintain a biennial inventory "of all stocks . . . on hand,"[9] as well as "a complete and accurate record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of by him[.]" 21 U.S.C. §§ 827(a)(1) and (3).[10] The records must be maintained "separately from all other records of the registrant . . . and . . . shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General." 21 U.S.C. § 827(b). Failure to comply with these record-keeping requirements is an unlawful act subject to penalties of up to $10,000 per violation. 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

Under the facts outlined above, it is undisputed that defendant has failed to comply with the record-keeping requirements of the Act. He has committed one (1) violation of the requirement to maintain a biennial inventory (Count III) and fourteen (14) violations of the requirement to maintain purchase records (Count I).

Because he kept no dispensing records, it is difficult to determine the number of violations attributable to that failure (Count II). Plaintiff, however, has suggested some alternatives.

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[8] The Act is often referred to in case law as the "Controlled Substances Act."

[9] For purposes of the biennial inventory, substances are broadly deemed to be "on hand" if they "are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples." 21 C.F.R. § 1304.11(a).

[10] *See* 21 C.F.R. § 1304.22(c) (outlining in detail the record-keeping requirements for dispensers of controlled substances).

First, plaintiff points to courts[11] that have based the number of record-keeping violations on the number of different controlled substances possessed. *See United States v. Green Drugs*, 905 F.2d 694, 695 (3d Cir. 1990) (three controlled substances, assessed at $2,000 each, for a total penalty of $6,000); *United States v. Poulin*, 926 F. Supp. 246 (D. Mass. 1996) (eighteen controlled substances, assessed at $1,000 each, for a total penalty of $18,000 for failing to keep accurate records (plus other penalties for different violations)); *United States v. Queen Village Pharmacy*, Civ. A. No. 89-2778, 1990 WL 165907, at *4 (E.D. Pa. Oct. 25, 1990) (two controlled substances, separately penalized, plus a penalty for failure to keep a biennial record).[12] Here, plaintiff asserts that there are two controlled substances: hydrocodone/APAP 10/500 mg and hydrocodone/APAP 10/325 mg.

Using the number of controlled substances (in this case: two) does not adequately account for an important underlying purpose of the Act – that is "control through record keeping." *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala. 1996) (quoting *United States v. Greenberg*, 334 F. Supp. 364, 366-67 (W.D. Pa. 1971)). The Act and its supporting regulations require records to account for the flow of controlled substances under a registrant's control, so as to guard against "the diversion of drugs from legitimate channels to illegitimate channels." *United States v. Moore*, 423 U.S. 122, 135, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975). A person should not be able to artificially manipulate the number of violations for which he is

[11] Many of the cases cited herein were decided at a time when the Act imposed strict liability for violations and permitted civil penalties of up to $25,000 per violation. The Act has since been amended so that negligent failure to keep records is a violation, subject to penalties up to $10,000. However, the legal principles of each case are still relevant for purposes of the instant analysis.

[12] Although *Queen Village Pharmacy* did assess one penalty for failure to keep records on Preludin 75 mg tablets and another for failure to keep records on Ritalin 20 mg tablets, it actually calculated the amount of the penalty based on the number of individual tablets, which also resembles the third alternative suggested by plaintiff.

liable by simply limiting the number of controlled substances he purchases and dispenses. The Court rejects this alternative.

Second, plaintiff cites another instance, where a defendant failed to include in its 37-page drug log the addresses of the patients to whom the drugs were dispensed. The court found the defendant liable for thirty-seven (37) violations (one for each page of the log), despite the fact that the failure to record addresses had occurred "on hundreds of occasions[.]" *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310, 314 (E.D. La. 1990). Based on that case, plaintiff asserts that this Court should assess a penalty for each of the sixty (60) dispensing entries listed in defendant's "Meds Out" log.

This Court rejects using the "Meds Out" log as a basis for determining a number of violations for the simple reason that this log appears to have been fabricated for purposes of this litigation, and there is no independent way to verify its entries.[13] Moreover, if *Clinical Leasing* were used as a template, then it would seem that there would be only six (6) violations (one for each page of the "Meds Out" log), not the requested sixty (60) (one for each notation of hydrocodone dispensing).

Finally, plaintiff suggests assessing a civil penalty for each of the 11,500 hydrocodone tablets that are unaccounted for in any dispensing record.[14] There is support for this method in the case law. In *United States v. Stidham*, 938 F. Supp. 808 (S.D. Ala. 1996), among other violations, "defendant failed to record, at a minimum, a total of 16,877 doses of methadone[.]" *Id*. at 815. The court concluded that "each and every failure [to record]

[13] Although the entries in the "Meds In" log also seem to have been fabricated, they at least show some relationship to the information provided by Henry Schein, Inc. There is nothing to substantiate the entries in the "Meds Out" log.

[14] In making this particular argument, plaintiff relies upon *Clinical Leasing Services*, *supra*. However, the Court finds no guidance in that case and, instead, relies upon *Stidham*.

constitut[ed] an individual violation of the Act and [the regulations]." *Id*. The court also found "some 14 bottles of methadone equating to a minimum of 560 doses of methadone were unaccounted for, or another 560 violations of [the Act and the regulations]." *Id*.[15]

Here, the defendant's own failure to keep any records makes it impossible to determine a number of violations. In light of the Act's purposes, it seems entirely fair that all inferences be drawn against defendant and that the Court assume the worst-case scenario, namely, that the 11,500 tablets were dispensed one at a time. This conclusion seems equally justifiable where, as here, defendant's criminal record suggests that he was "dispensing" these controlled substances to himself.[16] Therefore, as in *Stidham*, this Court finds that each individual hydrocodone tablet (i.e., each dose) constitutes a violation of the record-keeping statute, for a total of 11,500 violations.

III. CONCLUSION

In light of the above discussion, the Court grants summary judgment as to liability in favor of plaintiff and against defendant for unlawful acts under 21 U.S.C. § 842(a)(5), as follows:

1. On Count I, the Court finds defendant liable for fourteen (14) violations of 21 U.S.C. § 827(a)(3) and 21 C.F.R. § 1304.22(c), by failing to maintain purchase records for hydrocodone, a Schedule III controlled substance;

[15] In fact, it appears that the court in *Stidham* actually counted the 560 doses twice, for violations of two different regulations. *See Stidham*, 938 F. Supp. at 815 and 816.

[16] In enacting this statute, "[Congress] was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *Moore*, 423 U.S. at 135. Although there is no evidence here that defendant was selling these drugs illegally, even his own personal use of the drugs amounted to a diversion from legitimate to illegitimate channels.

2. On Count II, the Court finds defendant liable for 11,500 violations of 21 U.S.C. 827(a)(3) and 21 C.F.R. §1304.22(c), by failing to maintain dispensing records for hydrocodone, a Schedule III controlled substance; and
3. On Count III, the Court finds defendant liable for one (1) violation of 21 U.S.C. § 827(a)(1) and 21 C.F.R. § 1304.11(c), by failing to maintain a biennial inventory of his stock of controlled substances on hand.

IV. SUBSEQUENT PROCEEDINGS

The sole remaining issue is the amount of civil penalties to be assessed against defendant for these violations. In making this determination, courts consider the following four factors: (1) the willfulness of the violations; (2) whether, and to what extent the defendant profited from the illegal activity; (3) harm to the public; and (4) the financial capacity of the defendant to pay. *United States v. Poulin*, 926 F. Supp. at 253-54 (citing *United States v. Barbacoff*, 416 F. Supp. 606, 610 (D.D.C. 1976); *United States v. Queen Village Pharmacy*, 1990 WL 165907, at *2). These are matters for the Court to decide in a separate proceeding. *See Tull v. United States*, 481 U.S. 412, 427, 107 S. Ct. 1831, 95 L. Ed. 2d 365 (1987) (applying the Clean Water Act, and determining that "highly discretionary calculations that take into account multiple factors are necessary in order to set civil penalties . . . [and] are the kinds of calculations traditionally performed by judges.") (citing *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 442-43, 95 S. Ct. 2362, 45 L. Ed. 2d 280 (1975)).

The case is already set for a final pretrial conference on March 5, 2014, with a bench trial on March 17, 2014. These deadlines are retained and the Court will proceed to the penalty phase at that time.[17]

IT IS SO ORDERED.

Dated: January 22, 2014

HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE

[17] Of course, the parties remain free to enter into settlement discussions on their own, or to request the Court's assistance with the same, at any time.